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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,715	09/18/2003	Dimitrios Manoussakis	P-5808	4404
26253 7590 03/27/2009 David W. Highet, VP & Chief IP Counsel Becton, Dickinson and Company 1 Becton Drive MC 110 Franklin Lakes, NJ 07417-1880				
EXAMINER				
WRIGHT, PATRICIA KATHRYN				
ART UNIT		PAPER NUMBER		
1797				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/664,715

Applicant(s)

MANOUSSAKIS ET AL.

Examiner

P. Kathryn Wright

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 16-18, 20-24, 26-28 and 30-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14, 16-18, 20-24, 26-28 and 30-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Claims

1. This action is in response to papers filed February 20, 2009 in which claim 14 was amended. Claims 1-13 and 33-86 are currently withdrawn. The amendments have been thoroughly reviewed and entered.

Applicant's arguments have been thoroughly reviewed. Any objection/rejection not repeated herein has been withdrawn by the Office.

Claims 14, 16-18, 20-24, 26-28, and 30-32 are under prosecution.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 14, 16-18, and 20-24, 26-28 and 30-32 are again rejected under 35 U.S.C. 102(b) as being anticipated by Kessler (US Patent No. 4,350,593).

Kessler teaches a container (tube 12) having an upper end, a closed lower end, and a sidewall between the upper and lower ends having inner and outer walls (see col. 3, lines 53- Figs. 2-4). The tube includes a pierceable closure 14 therein (claim 31).

The only structure with respect to the claimed container and thixotropic gel in the claim is the recitation of a thixotropic gel located in contact with a portion of the inner wall of the container. The thixotropic gel of Kessler is specifically cited in Applicant's instant specification as capable of being advantageously used in the invention, see par.

[0033] of the instant specification. Kessler teaches a thixotropic gel 22 located inside at the closed lower end of the container contacting a portion of the inner wall (col. 1, line 56- col. 2, line 2; col. 3, line 54- col. 4, line 6; see also Figs. 2-3). Therefore, since the claimed and prior art gels are identical or substantially identical in structure or composition they must necessarily exhibit the same rheological properties under the same conditions. That is, the first region of the gel of Kessler inherently comprises:

a first region with at least about 80 vol. % of the gel (claim 14), the imaginary upper boundary exhibits a best fit plane within 10 degrees of a plane perpendicular to the longitudinal axis of the tube (claim 16), the distance between the first and second regions being between 8 to 21 mm (claims 17-18), the first region comprises about 80 to 95 vol. % of the gel (claim 20), the interior surface of the thixotropic gel at the intersection of the first and second regions exhibits a radius of curvature between about 4 and about 8 mm (claim 21), wherein a best-fit plane to the exposed surface of the first region facing the interior of the container exhibits an angle of 25 ° or less with a plane substantially perpendicular to the longitudinal axis of the container (claim 22), the exposed surface of the second region facing the interior of the container defines a best-fit plane exhibiting a 45 to 90° angle with a plane substantially perpendicular to the longitudinal axis of the container (claim 23), the best-fit plane to the exposed surface of the first region facing the interior of the container exhibits an angle of 90 to 140° with the best-fit plane to the surface of the second region facing the interior of the container (claim 24), wherein along a plane perpendicular to the longitudinal axis of the container located halfway between the average height of the exposed surface of the first region and the uppermost point of the second region, the second region exhibits 80 to 140°

circumferential contact with the inner surface (claim 26), wherein the entirety of the second region exhibits less than 180° circumferential contact with the inner wall (claim 27) and, wherein the entirety of the second region exhibits less than 120° circumferential contact with the inner wall (claim 28).

Response to Arguments

4. Applicant's arguments filed February 20, 2009 have been fully considered but they are not persuasive.

In response to the previous rejection of claims 14, 16-18, 20-24, 26-28 and 30-32 under 35 U.S.C. 102(b) as being anticipated by Kessler (US Patent No. 4,350,593), Applicant again argues that claim 14 is directed to a specific geometry (and not a composition or structure) for a thixotropic gel disposed in a container that overcomes potential gel movement issues. Applicant asserts that Kessler is completely silent in regard to the vol.% of gel in the first region.

The Examiner respectfully disagrees. As discussed above, the thixotropic gel of Kessler is specifically cited in the instant specification as capable of being advantageously used in the invention, see par. [0033] of the instant specification. The Examiner asserts that the claimed and prior art gels are identical or substantially identical in structure or composition. Therefore, the claimed and prior art gels must exhibit the same rheological properties under the same conditions, that is, the first region of Kessler must necessarily comprise the geometry of the gel as recited in the claims.

In addition, Applicant's specification recites the desired geometry of gel may be provided by disposing the thixotropic gel into the tube using a nozzle, then centrifuging

the tubes at a particular angle and speed to provide the desired geometry, see paragraph [0035]. Note the particular angle and speed is not disclosed in Applicant's original specification. Similarly, Kessler teaches filling container with a barrier material (same gel as claimed) such that the barrier material 22 is disposed with the surface 23 forming other than a plane perpendicular to the axis A of the tube 12, see Fig. 2. Kessler teaches the manner of making the invention includes introducing the barrier material 22 into the container, then testing for its bleed and yield stress (see Example 1). This test comprises storing the assembly 10 (i.e., thixotropic gel in the container 12) for a period of time and then ultra-centrifuging an aliquot of the barrier material 22. Thus, the gel of Kessler must inevitably comprise the geometry recited in the claims, since the claimed gel, and that of Kessler, are introduced into the container and centrifuged in the same manner.

Furthermore, Kessler recognizes the importance of the vast majority of the gel be at or near the bottom of the tube with a portion of the gel extending upward onto the inside surface so as overcome the yield stress of the barrier material and cause gel movement at the earliest possible stage of centrifugation so as to avoid rupture of cellular blood components.

Therefore, for the reasons delineated above, all pending claims are rejected under 35 U.S.C. 102(b) as being anticipated by Kessler (US Patent No. 4,350,593).

Conclusion

5. No claims allowed.
6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Wright whose telephone number is (571)272-2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

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Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PKW

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797